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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ROSEANNE SANCHEZ, et al.,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendants.

Case No. CV 15-1245-JFW (JEMx)

**DEFENDANT'S OFFER OF PROOF FOR EXPERT MATTHEW DAVIES, M.D.**

**Trial: May 5, 2015**

Pursuant to the Court's In Chambers Order of April 17, 2015 (Doc. 217), Defendant Boston Scientific Corporation ("Boston Scientific") submits the following offer of proof for its expert witness Matthew Davies, M.D..

# OFFER OF PROOF FOR MATHEW DAVIES, M.D.

## I. Curriculum Vitae, Expert Report, and Deposition Transcript of Matthew Davies, M.D.

Dr. Davies's curriculum vitae is attached hereto as Exhibit 1. Dr. Davies's expert report pertaining to Mrs. Sanchez is attached hereto as Exhibit 2. A complete list of materials he reviewed in forming his opinions are attached as Exhibit B to his Expert Report. A mini-script of Dr. Davies's deposition taken in this matter is attached hereto as Exhibit 3.

## II. Qualifications of Matthew Davies, M.D.

Dr. Davies is the Director of the Division of Urogynecology and Minimally Invasive Surgery at Penn State Milton S. Hershey Medical Center. He also serves as an Associate Director for the Obstetrics and Gynecology residency program at the Penn State Hershey Medical Center, the Director of the Obstetrics and Gynecology Grand Rounds, and Chief of Obstetrics. He received a Ph.D. in Chemistry at the University of California at Berkeley in 1985. He received a Doctor of Medicine in 1989 from the Pennsylvania State University College of Medicine, and he completed a residency in Obstetrics and Gynecology in 1993 at The Milton S. Hershey Medical Center. He is board certified in Obstetrics and Gynecology and has a subspecialty certification in Female Pelvic Medicine and Reconstructive Surgery.

His clinical practice is focused on treatment of women with pelvic floor disorders, and the majority of women he treat suffer from urinary incontinence and/or pelvic organ prolapse. Dr. Davies has extensive experience treating these conditions and utilizes both mesh and non-mesh procedures.

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## III. Opinions of Dr. Davies:

- **Opinion # 1: SUI and POP Can Have A Significant Impact on A Woman's Life.**

A. Explanation of SUI and Impact on a Woman's Life

Dr. Davies will testify regarding the condition of SUI, which is the leakage of urine during stress activities. He will testify that stress urinary incontinence occurs when the urethral support provided by the vagina weakens, which does not allow for full closing of the urethra during stressful activities. He will testify that these activities include coughing, sneezing, exercise and laughing. He will testify that stress urinary incontinence typically worsens over time and does not improve without treatment. (Expert Rep., p. 2.)

Dr. Davies will testify regarding the finding in the 2013 Cochrane Review for surgical management of pelvic organ prolapse in women, that prolapse is seen in 40-60% of women on examination. And a woman's lifetime risk of stress urinary incontinence is estimated to be up to 50%. (Expert Rep., pp. 1-2; Retropubic versus transobturator midurethral slings for stress incontinence, Richter, H, et al, New Eng J Med 1-11 (2010).)

Dr. Davies will testify that urinary incontinence can have a devastating effect on a woman's quality of life because the physical effects of stress urinary incontinence can include the need to wear absorbent pads (adult diapers in severe cases), leaking urine onto clothing and the body, urinating during intercourse, and a foul odor, among others. Emotional effects of both stress urinary incontinence and prolapse can include avoidance of personal and professional situations, negative effect on sexual relations, feelings of self-consciousness, and a negative body image. (Expert Rep., p. 3.)

B. Explanation of POP and Impact on a Woman's Life

Dr. Davies will testify regarding the condition of POP, and will explain the different areas within the vagina, and the different support structures attached to each area. He will testify that any of these structures can weaken and lead to prolapse. He will testify that the most common area to weaken is the anterior vaginal wall, or the wall that is under the bladder. Weakness in this area leads to a dropped bladder known as a cystocele. The uppermost part of the vagina, where either the cervix is located (if a woman has not had a hysterectomy) or the vagina vault or cuff is located (if a woman has undergone hysterectomy) can also weaken. This apical area of prolapse is known as a uterine or cuff prolapse, respectively. When one looks at these two compartments separately or together as part of a larger picture of prolapse, they comprise 85% of the cases of pelvic organ prolapse. The back wall of the vagina, which is over the rectum, can also weaken and lead to rectal prolapse, otherwise known as a rectocele. This occurs in 10-15% of cases of prolapse. Finally, there are rarer hernias in which the small bowel can push through a weakened area of the vagina resulting in an enterocele.

Dr. Davies will testify regarding the diagnosis of prolapse, which is graded on a system ranging from Stage 0-4. Many women seek medical treatment once the prolapse reaches Stage 2. (Expert Rep., p. 2.)

Dr. Davies will testify regarding symptoms of prolapse that can include a feeling of pelvic pain or pressure, a sensation of pelvic "heaviness," low back pain, bloody discharge, bleeding during and/or after intercourse, sexual dysfunction, painful intercourse, urinary dysfunction, urinary tract infections, and bowel dysfunction. He will testify that in severe cases, the prolapse may protrude beyond the vaginal opening, and the woman may need to push the prolapsed organ(s) back in the vagina to urinate or defecate normally, or to engage in normal sexual relations. He will testify that in some cases of prolapse, simple acts such as standing, sitting, or walking

can become very uncomfortable, even painful. He will testify that prolapse does not improve without treatment and typically worsens over time. (Expert Rep., p. 2.)

Dr. Davies will testify that pelvic organ prolapse can have a devastating effect on a woman's quality of life. He will testify that emotional effects of prolapse can include avoidance of personal and professional situations, negative effect on sexual relations, feelings of self-consciousness, and a negative body image. (Expert Rep., p. 3.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing the symptoms and conditions associated with SUI and POP, those suffered by Mrs. Sanchez prior to her implant, why surgical treatment is a necessary choice for some women, and why surgery, including the Pinnacle, was necessary and appropriate for Mrs. Sanchez.

- **Opinion # 2: Polypropylene Mesh Is Safe and Effective for Permanent Implantation.**

A. Polypropylene Mesh Does Not Cause a Degradative or Infectious Process

Dr. Davies will testify that the body's healing response to polypropylene, specifically Advantage and Polyform mesh, is normal and expected. He will testify that he has not seen a systematic degradative or infectious process of polypropylene mesh. (Expert Rep., p. 8.)

B. Polypropylene Mesh Does Not Cause Cancer

Dr. Davies will testify that he has never seen a patient develop cancer in connection with polypropylene mesh. He will testify that such theories are not supported by long term clinical use or clinical study of polypropylene surgical mesh. (Expert Rep., p. 8.)

C. Polypropylene Mesh Contracture Is Not Extreme And Does Not Cause Chronic Pain

Dr. Davies will testify that he does not believe that mesh contracture is extreme nor does it cause chronic pain and dyspareunia. He will testify that scar contracture is limited, and that the overwhelmingly majority of patients receiving Type I polypropylene mesh implants, including the Pinnacle and Advantage Fit, do not report pain beyond the immediate post-operative period. (Expert Rep., p. 10.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This opinion is relevant to this matter because it provides information concerning Dr. Davies' personal clinical experience with his use of polypropylene mesh in surgical procedures and the safety and efficacy of the Pinnacle.

- **Opinion # 3: The Pinnacle Was A Safe and Effective Product For Treatment of POP Based On Clinical Studies and Historical Surgical Methods of POP Repair**

Dr. Davies will testify about patient treatment options for prolapse. In particular, he will testify that a patient experiencing pelvic organ prolapse has four options: no treatment, physical therapy, a pessary, or surgery. No getting any treatment is typically not an option for patients presenting with bothersome prolapse symptoMrs. Physical therapy is also typically ineffective. A pessary is an option for some women, but many women find them uncomfortable and are bothered by the discharge they create and the need for removal prior to intercourse. For symptomatic patients, surgery is generally the best option. (Expert Rep., p. 5.)

Dr. Davies will also testify that although non-surgical options exist for treatment of stress urinary incontinence, these options are largely ineffective. Such

options include timed voiding, pelvic floor strengthening exercise, and lifestyle modifications including weight loss. (Expert Rep., p. 3.)

He will testify about the surgical options for treatment of pelvic organ prolapse. Surgery can be performed via an abdominal or vaginal route. For many years an abdominal incision was used to place a polypropylene mesh from the top of the vagina or cervix to the sacrum. These procedures were known as a sacral colpopexy or sacral cervicopexy, respectively, and hysterectomy is required in both instances. Whether the prolapse repair is performed abdominally or vaginally, the uterosacral or sacrospinous ligaments have historically been used as a fixation point for the upper vagina to provide apical support. (Expert Rep., p. 5.)

He will testify that for prolapse occurring in the apical compartment, the sacral colpopexy has long been considered an appropriate treatment option. Originally performed through an open abdominal incision, it more recently has been performed laparoscopically or robotically. Sacral colpopexy adequately addresses apical prolapse, but this procedure does not provide primary support to the anterior or posterior vaginal wall. In addition, he will testify that rectal prolapse cannot be addressed in this procedure. And he will explain how abdominal procedures are not an option for a certain population of patients. (Expert Rep., p. 5.)

He will testify about the safety and efficacy of the vaginal approach for the repair and treatment of prolapse. More specifically, he will testify that the vaginal approach to prolapse repair is widely used to eliminate the potentially life-threatening complications associated with abdominal surgery, which include bowel and vascular injury. Vaginal approach to prolapse repair involves use of the patient's native tissues, insertion of a biological material, or use of a synthetic mesh. When using a synthetic mesh, it is understood that that the mesh is permanent. Physicians have understood the permanence of synthetic implantable mesh since its inception. (Expert Rep., pp. 5-6.)

Dr. Davies will explain that at the time Boston Scientific sought FDA clearance of the Pinnacle Pelvic Floor Repair System, use of a permanent, macroporous, monofilament polypropylene mesh to surgically augment soft tissue defects, specifically pelvic organ prolapse, was not a new idea. He will testify that polypropylene meshes had been used for decades in abdominal repair of hernias (including Boston Scientific's own Trelex mesh) and prolapse with evidence of safety and efficacy. Hernia Repair with Marlex Mesh, Arch Surg 84 (), F. Usher, March 1962:73-76; Def. Ex. 530, G. Di Vita et al, Acute Inflammatory Response After Inguinal and Incisional Hernia Repair with Implantation of Polypropylene Mesh of Different Size, Langenbecks Arch Surg (2005) 390:306-311, Def. Ex. 584; Marlex Gauze Hammock Sling Operation of Cooper's Ligament Attachment in the Management of Recurrent Urinary Stress Incontinence, F. Bryans, Am J Obstet Gynecol, 133:292, 1979, Def. Ex. 587; Correction of Rectal Procidentia by use of Polypropylene Mesh (Marlex), M. Lomas and H. Cooperman, Dis. Col. & Rect. Vol 15 No. 6, Nov.Dec. 1972:416-419, Def. Ex. 583; The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall T. Julian, Am. J. Obstet. & Gynecol. (1996) 175: 1472-75, Def. Ex. 499.

In addition, early studies of other vaginal prolapse meshes with mesh characteristics similar to the mesh used in the Pinnacle demonstrated safety and efficacy. (Expert Rep., p. 7; Transvaginal Repair of Genital Prolapse: Preliminary Results of a New Tension-Free Vaginal Mesh (Prolift™ technique) - A Case Series Multicentric Study, B. Fatton, J. Amblard, et al, Int Urogynecol J (2007) 18:743-752, January 1, 2007, Def. Ex. 443; Anterior Colporrhaphy Reinforced with Marlex Mesh for the Treatment of Cystoceles, C.G. Flood, H.P. Drutz and L. Waja, Int Urogynecol J (1998) 9:200-204, January 1, 1998, Def. Ex. 425; Efficacy and Outcome of Anterior Vaginal Wall Repair Using Polypropylene Mesh (Gynemesh), H. Jo, J. Kim, et al, J. Obstet. Gynaecol. Res. Vol. 33, No. 5: 700-704, October 2007, October 1, 2007, Def.

Ex. 448.) Vaginal mesh kits were designed to be less invasive, provide for more reproducible outcomes, and reduce complications associated with abdominal surgery. (Expert Rep., p. 7.)

Dr. Davies will testify that suture-based repairs using the patient's own tissue are common treatment options employed to correct anterior prolapse (cystocele) or rectal prolapse (rectocele). He will testify that the most-common suture-based operation is the colporrhaphy. He will testify that failure rates associated with anterior colporrhaphy approach 50% at one year follow up in patients with grade 2 or higher prolapse, which is why gynecologic surgeons looked to reinforcement of prolapse repair with grafts. (Epidemiology of Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence, Obstet & Gynec; A. Olsen, V. Smith, et al, Vol 89, No 4, Apr 1997:501-506, April 1, 1997, Def. Ex. 424; Risk Factors for Prolapse Recurrence after Vaginal Repair, J. Whiteside, A. Weber, L. Meyn and M. Walters, Am J Obstet Gynec (2004) 191, 1533-8, Def. Ex. 437.) He will testify that graft options include biologics, allografts, and synthetic mesh, and about the limitations associated with each approach. (Expert Rep., p. 6.)

Dr. Davies will testify about medical literature that compares various types of surgical repair for prolapse. He will testify that between 2007 and 2011, multiple randomized, controlled trials and meta-analyses comparing traditional prolapse repair to synthetic mesh repair were published. *See, e.g.,* A Randomized Comparison of Polypropylene Mesh Surgery with Site-Specific Surgery in the Treatment of Cystocoele, A.A. Sivaslioglu, E. Enlubilgin and I. Dolen,, Int Urogynecol J (2008) 19:467-471, Def. Ex. 451; Outcome After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial, J. Nguyen and R. Burchette, Obstet Gynecol 2008; 111:891-8, Def. Ex. 453; Vaginal Repair with Mesh Versus Colporrhaphy for Prolapse: A Randomised Controlled Trial, M. Carey et al, BJOG 2009; 116:1380-1386, Def. Ex. 545; Laparoscopic Sacrocolpopexy Versus Transvaginal Mesh for

Recurrent Pelvic Organ Prolapse, C. Iglesia, D. Hale and V. Lucente, Int Urogynecol J (2013) 24:363-370, Def. Ex. 486; Trocar-Guided Mesh Compared With Conventional Vaginal Repair in Recurrent Prolapse: A Randomized Controlled Trial, M. Withagen, A. Milani, et al, Obstet Gynecol 2011;117:242-50, Def. Ex. 472; Anterior Colporrhaphy Versus Transvaginal Mesh for Pelvic-Organ Prolapse, D. Altman, T. Vayrynen, et al, N Engl J Med 364;19:1827 - 1836; May 2011, Def. Ex. 475. Dr. Davies will testify about these studies and that they demonstrate that mesh provides superior prolapse support by exam, without compromising quality of life measures. (Synthetic mesh in the surgical repair of pelvic organ prolapse: current status and future directions, T. Keys et al, Urology. (2012) 80: 237-43, Def. Ex. 522. He will testify that in addition, several of these studies demonstrate that de novo dyspareunia or less resolution in prolapse symptoms and sexual function occurs more often following anterior colporrhaphy than prolapse repair using vaginal mesh. Outcome After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial, J. Nguyen and R. Burchette, Obstet Gynecol 2008; 111:891-8, April 1, 2008, Def. Ex. 453; Symptom Resolution and Sexual Function after Anterior Vaginal Wall Repair With or Without Polypropylene Mesh, K. Nieminen, R. Hiltunen, et al, Int Urogynecol J (2008) 19:1611-1616, Def. Ex. 455; A Randomized Comparison of Polypropylene Mesh Surgery with Site-Specific Surgery in the Treatment of Cystocele, A. Sivaslioglu, E. Unlubilgin and I. Dolen, Int. Urogynecol. Journal; Vol. 19; pgs. 467-471, Def. Ex. 547.

He will testify about another study that found that pre-implant urinary symptoms and pelvic pain improved more often following mesh repair than site-specific cystocele repair. A Randomized Comparison of Polypropylene Mesh Surgery with Site-Specific Surgery in the Treatment of Cystocele, A. Sivaslioglu, E. Unlubilgin and I. Dolen, Int. Urogynecol. Journal; Vol. 19; pgs. 467-471, Def. Ex.

547. This same study observed no mesh shrinkage in the mesh group. (Expert Rep., p. 6.)

Dr. Davies will also testify about studies published specific to the Pinnacle. He will testify about the variability of complication rates and the factors affecting the same. He will testify that the complication rates vary among these studies based on surgeon technique and individual patient circumstances. He will testify about the results of these studies, and that the study with the longest follow-up, and involving the largest sample size, shows that vast majority of patients experience safe and effective resolution of their prolapse with the Pinnacle. (Expert Rep., p. 7.)

Dr. Davies will testify that Pinnacle's entrance into the pelvic floor repair kit market signaled a different method to prolapse repair. He will testify that the Pinnacle did not employ trocars and utilized a smaller piece of mesh—albeit the same mesh that had been used in pelvic surgery for more than a decade. He will testify that at this time, the Capio had a long history of safe use in suture-based pelvic floor repair and was the logical delivery device to accompany the Pinnacle. He will testify about the development of the Pinnacle, and that the sacrospinous ligaments and arcus tenineus had historically been fixation points for other prolapse repairs and were an appropriate anchor point for the Pinnacle. He will testify that based upon the long, safe history of Trelex mesh, Advantage and Polyform mesh, use of the Capio as the delivery device, and utilizing the sacrospinous ligaments and arcus tendineus as fixation structures, the Pinnacle was a different, yet improved, method of prolapse repair. (Expert Rep., pp. 7-8.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing the various treatment options available for SUI and POP, why surgical treatment is a necessary choice for some

women, the various risks and benefits associated with each of these procedures, and why surgery, including the Pinnacle, was necessary and appropriate for Mrs. Sanchez. In addition this opinion is relevant because it explains the clinical evidence available and relied upon for the safety and efficacy of the Pinnacle.

- **Opinion # 4: The Advantage Is A Safe And Effective Treatment Option for SUI.**

Dr. Davies will explain that the majority of women with bothersome stress urinary incontinence require surgical treatment. He will testify about surgical procedures used to treat stress urinary incontinence, and how they include the needle suspensions of the vagina (e.g., Pereyra-Raz suspension), the retropubic urethropexies (e.g., Burch), placement of a fascial suburethral sling (aka pubovaginal sling), and placement of a polypropylene mid-urethral sling.

Dr. Davies will testify that the first polypropylene mesh mid-urethral sling was cleared by the FDA in 1996. Boston Scientific received FDA clearance for its first polypropylene mid-urethral sling, the Advantage, in 2002. Monofilament, macroporous polypropylene was an acceptable material to use in the Advantage sling. He will testify that at that time, clinical literature established that treatment of stress urinary incontinence with a macroporous, monofilament polypropylene mid-urethral sling had cure rates similar or superior to non-mesh incontinence surgeries, including the gold standard at that time—the Burch. A Systematic Review of Tension-Free Urethropexy for Stress Urinary Incontinence: Intravaginal Slingplasty and the Tension-Free Vaginal Tape Procedures, T. Merlin, E. Arnold, P. Petros, et al, BJU International (2001), 88, 871-880, August 28, 2001; Def. Ex. 431; Burch Colposuspension and Tension-Free Vaginal Tape in the Management of Stress Urinary Incontinence in Women, A. Liapis, P. Bakas and G. Creatsas, Eur Urol 41 (2002):469-473, January 22, 2002; Def. Ex. 432.

He will also testify about the long-term data that was also available to support a finding of safety and efficacy for this therapy. (An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence, U. Ulmsten et al, Int. Urogynecol. Journal (1996); Vol. 7; pgs. 81-86; Def. Ex. 553; A Three-year Follow Up of Tension Free Vaginal Tape for Surgical Treatment of Female Stress Urinary Incontinence, I. Olsson and U.B. Kroon, Gynecol Obstet Invest 1999;48:267-269, June 19, 1999; Def. Ex. 427.) In addition, the physicians performing these procedures reported that the sling was less invasive and had lower morbidities than the Burch, pubovaginal sling, or other traditional surgeries. (Expert Rep., p. 3.)

Dr. Davies will testify about the long-term data available today that establishes the long-term safety and efficacy of mid-urethral slings like the Advantage Fit implanted in Mrs. Sanchez. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence, Nilsson, C, et al., Int Urogynecol J (2013) 24:1265-69, April 6, 2013; Def. Ex. 487. Long-term data was available at the time of Mrs. Sanchez' pelvic mesh procedures and was well known in the gynecologic community. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence, Nilsson, C, et al., Int Urogynecol J (2008) 19:1043-47. (Expert Rep., p. 4.)

Dr. Davies will testify that long-term data also confirms the superiority of mid-urethral slings like the Advantage Fit over traditional incontinence surgery, including the Burch and pubovaginal sling. (Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence, Novara, G, et al., European Urology 58 (Aug. 2010) 218-38; Def. Ex. 618.) In the most-recent Cochrane review of minimally invasive synthetic suburethral sling operations for SUI, Type I polypropylene mid-urethral slings were found to be superior to all alternative surgical treatment options. (Minimally invasive synthetic suburethral sling operations

for stress urinary incontinence in women, Ogah, J, et al., (2010, Issue 1), January 1, 2010; Def. Ex. 462.) Dr. Davies will testify to the findings of this review, which include the following:

- Polypropylene mid-urethral slings are as effective as traditional slings, but have a shorter operating time and less voiding dysfunction and *de novo* urgency;
- Polypropylene mid-urethral slings are as effective as the traditional Burch, but have few peri-operative complications, a shorter operative time and hospital stay, and less voiding dysfunction;
- Compared to laparoscopic colposuspension, polypropylene mid-urethral slings have significantly less *de novo* urgency and urge incontinence, a shorter operating time, hospital stay and return to normal activities; and
- Monofilament slings had significantly higher objective cure than multi-filament slings, with few mesh erosions.

(Expert Rep., p. 4; Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women, Ogah, J, et al., (2010, Issue 1), January 1, 2010; Def. Ex. 462.)

He will testify that the leading medical societies for female pelvic surgery view polypropylene mid-urethral slings like the Advantage Fit as the gold standard of care for treatment of SUI, and he also holds this view. In addition, the clinical literature reports safe and efficacious use of the Advantage slings, and an Obstetrics & Gynecology Devices Panel convened by the FDA has stated, "[T]he safety and effectiveness of these devices [retropubic and transobturator suburethral slings] is well-established." *See* AUGS Position statement on Restriction of Surgical Options for Pelvic Floor Disorders, March 3, 2013, Exhiibt 390; AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence, AUA Webpage November 2011; Def. Ex. 470; Three-year results from a randomized

trial of a retropubic mid-urethral sling versus the Miniarc single incision sling for stress urinary incontinence, Basu, M, et al., Int Urogynecol J (2013), April 28, 2013; Def. Ex. 489; A series of Advantage suburethral slings, Renganathan, A, et al., J Obstet and Gynaecol (Aug. 2011); 31:521-23; Def. Ex. 416; FDA 24-Hour Summary, Surgical Mesh Panel Meeting (September 8-9, 2011). He will confirm there is no dispute that Mrs. Sanchez received the gold standard of care for treatment of her SUI. (Expert Rep., pp. 4-5.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing the various treatment options available for SUI and POP, why surgical treatment is a necessary choice for some women, the various risks and benefits associated with each of these procedures, and why surgery, including the Advantage, was necessary and appropriate for Mrs. Sanchez. In addition this opinion is relevant because it explains the clinical evidence available and relied upon for the safety and efficacy of the Advantage. This opinion is also relevant because it speaks to Boston Scientific's meeting of its duty of care in its warning of the risks associated with the Advantage.

- **Opinion # 5: The Risks of Polypropylene for Vaginal Repairs Are Similar to Other Treatment Options**

Dr. Davies will testify that the risks of vaginal prolapse mesh compared to native tissue or biologic prolapse repair, with the exception of erosion, are the same. (And regarding biologic prolapse repair, this procedure also carries the risk of erosion.) He will testify that these risks include the risk of injury to vessels or internal organs such as the bowel or the bladder, or injury to the ureters carrying the urine from the kidneys down to the bladder. He will testify that there could also be the risk

of inflammation, infection, bleeding, discomfort, pain, dyspareunia, recurrent or de novo urinary incontinence and/or pelvic organ prolapse, urinary dysfunction including urinary retention, vaginal discharge, vaginal shortening, nerve injury, and constipation or other bowel dysfunction. (Expert Rep., p. 8.)

Dr. Davies will testify that these risks are not specific to Pinnacle, but rather exist for all surgical prolapse surgeries—and have been known for decades. (Expert Rep., p. 8.)

A. Directions For Use Adequately Warn of All Potential Mesh Risks

Dr. Davies will testify that the Directions For Use that accompany the Pinnacle adequately warns of all potential mesh risks. He will testify that the Directions For Use further warns that tissue responses, including vaginal extrusion or erosion or exposure, migration of the device, foreign body reaction, and inflammation will require removal or revision of the mesh. (Expert Rep., p. 8; Def. Ex. 6.) He will testify that the Directions For Use further warns that tissue responses, including vaginal erosion or exposure, migration of the device, foreign body reaction, and inflammation will require removal or revision of the mesh. (Expert Rep., p. 8; Def. Ex. 6.) Dr. Davies will testify that the Directions For Use for Boston Scientific's pelvic mesh devices, including the Pinnacle identify "mesh and/or tissue contracture" as a potential adverse event and warn the user, "[a]void excess tensioning of the mesh when positioning to avoid over correction of the defect." (Expert Rep., pp. 9-10; Def. Ex. 6.)

Dr. Davies will explain that the Directions for Use for the Pinnacle warn of the potential complications of dyspareunia, pain, and vaginal shortening or stenosis. Davies Dep. at 254:1-7, 255:5-8, 255:12-15, 257:13-15; Def. Ex. 6.

Dr. Davies will testify that the Directions For Use for the Advantage Fit adequately warns of all potential risks, including extrusion or erosion. (Expert Rep., p. 8; Def. Ex. 7.) Dr. Davies will testify that the DFU for the Advantage Fit warns,

"[u]ser should note the importance of placing the mesh tension free under mid-urethra." Mesh that is appropriately tensioned will correct the prolapse and/or SUI without adverse sequelae. (Expert Rep., pp. 9-10; Def. Ex. 7.)

B. The Risks of Pinnacle Surgery Are The Same As Most Other Surgeries Intended For Treatment of POP

Dr. Davies will testify that the risks of vaginal prolapse mesh compared to native tissue or biologic prolapse repair, with the exception of erosion, are the same. (And regarding biologic prolapse repair, this procedure also carries the risk of erosion.) He will also testify that these risks include the risk of injury to vessels or internal organs such as the bowel or the bladder, or injury to the ureters carrying the urine from the kidneys down to the bladder. There could also be the risk of inflammation, infection, bleeding, discomfort, pain, dyspareunia, recurrent or de novo urinary incontinence and/or pelvic organ prolapse, urinary dysfunction including urinary retention, vaginal discharge, vaginal shortening, nerve injury, and constipation or other bowel dysfunction. (Expert Rep., p. 8.)

Dr. Davies will testify that these risks are not specific to Pinnacle, but rather exist for all surgical prolapse surgeries—and have been known for decades. (Expert Rep., p. 8.)

As referenced above, nerve injury is a risk with all pelvic surgeries. This risk has been present since surgeons began performing pelvic surgery and continues to exist today. Nerve entrapment is a rare event that can occur following a surgery using mesh, but such an event only occurs in the event of a mesh malplacement. Implanted mesh will experience tissue in-growth and development of new microscopic nerves to nourish the new tissue, but this is a different phenomenon than nerve entrapment. (Expert Rep., pp. 8-9.)

Dr. Davies will testify that the most-meaningful complication rate is the rate specific to the surgeon, as rates of complications vary widely from surgeon-to-surgeon

and study-to-study. He will also testify that as with any surgery, a surgeon should perform his or her due diligence to become familiar with all of the risks, and rates of the risks, attendant to that surgery. He will testify that this information is published in the publicly-available clinical literature and is discussed at medical conferences, among colleagues, and at training courses, among other foruMrs. (Expert Rep., p. 9.)

Dr. Davies will testify that the only risk unique to mesh-based repairs is mesh erosion. Even then, erosion can occur following a native tissue prolapse repair if permanent sutures are used. Erosion means that the mesh is no longer just in the compartment where it was placed, but rather it has worked its way into a neighboring territory or the healing of the incision was inadequate and it opened back up, exposing the mesh to that area. He will testify that this complication has been given many different terminologies, including mesh exposure, mesh erosion or mesh extrusion. While sometimes true mesh erosion can occur into surrounding organs such as urethra, bowel or bladder, such an outcome is rare and is the exception to the rule. He will testify that when one talks about mesh erosion (which is actually mesh exposure), mostly physicians are referring to a small opening at the vaginal incision where the mesh is now exposed to the lumen of the vagina. He views mesh exposure as a healing issue. He will testify that mesh exposure is not an indication of a defect in the device. In many cases the exposure is asymptomatic and can be treated with estrogen cream or excision in the office. (Expert Rep., p. 9.)

Dr. Davies will testify that recent long-term data demonstrates that abdominal mesh-based prolapse repairs have erosion rates similar or higher to those of the vaginal mesh prolapse surgeries (around 11%), with higher failure rates than those reported for vaginal mesh prolapse surgeries (22-27% for anatomic failure and 24-29% for symptomatic failure). Long Term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse, I. Nygaard, L. Brubaker, et al, JAMA, Will 15, 2013 - Vol 309, No. 19:2016-2024; Def. Ex. 490.) He will also testify that

abdominal surgery is invasive, and there is a higher incidence of bowel injury or bowel obstruction with abdominal mesh. He will also testify that these complications are unique to the abdominal mesh-based repairs and are potentially more serious for the patient and more difficult to treat. Abdominally-placed mesh also carries a greater risk of injury to the common, internal, and external iliac vessels—a complication that is rarer with transvaginal surgery. (Expert Rep., p. 9.)

He will testify that the risk of mesh/tissue contraction is well known and has been known since general surgeons began using polypropylene mesh in hernia repair. He will testify that surgeons understand that the tissue ingrowth process will result in some degree of scar contracture, and the mesh is appropriately tensioned to account for such an event. (Expert Rep., pp. 9-10.)

He will testify regarding the multi-center study he authored that evaluated 213 patients implanted with the Pinnacle for a mean of 27.2 months (range of 12 -43 months). (Expert Rep. pp. 6-7; Davies Dep. at 18:18-19:23; Multi-Center Retrospective Clinical Evaluation of the Long Term Outcomes Following Pelvic Organ Prolapse Repair Using Pinnacle PFR Kit, Female Pelvic Medicine & Reconstructive Surgery, P. Rosenblatt, et al, Vol. 18, No. 8 Supp. 1, September/October 2012:S153; Def. Ex. 612.) He will testify that in that study, no patient reported recurrent prolapse, thus demonstrating that Pinnacle is effective in the long term. The study results also reflect a good safety profile with a low complication rate: 4.2% of patients experienced mesh exposure; 0.9% of patients experienced implant infection; and 0.9% of patients experienced voiding difficulty. While this is an acceptable complication rate, and likely a rate in line with the majority of Pinnacle users, the most-important rate to discuss with a patient is the rate specific to her surgeon. (Expert Rep., pp. 6-7.)

Dr. Davies will testify that the Pinnacle is not associated with any new risks to patients that he had not previously encountered with other pelvic floor surgeries. He

will testify that in his clinical practice, the Pinnacle reduced the risk of many complications he encountered in alternative prolapse surgeries and provided a safe, effective, and less invasive alternative to traditional prolapse repair. Both the Pinnacle and Advantage Fit successfully withstand the forces exerted on the pelvic floor and are durable in the long-term. (Expert Rep., p. 10.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing the various treatment options available for SUI and POP, and explains the various risks and benefits associated with each of these procedures. In addition, this opinion is relevant because it explains the clinical evidence available and relied upon for the safety and efficacy of the Pinnacle. This opinion is also relevant because it speaks to Boston Scientific's meeting of its duty of care in its warning of the risks associated with the Pinnacle.

- **Opinion # 6: Mrs. Sanchez's POP and SUI Symptoms Were Significant Enough To Require Surgical Treatment**

He will testify that Mrs. Sanchez presented to Dr. Kerri Wiltchik on December 9, 2009 complaining that her bladder was lower than usual and that she had occasional loss of urine with activity, as well as urinary frequency. He will testify that she was found to have a grade 2 cystocele, which had become symptomatic. On this visit, Mrs. Sanchez also reported pelvic pain, vaginal discharge, constipation, anxiety and depression. (Expert Rep., p. 10; Def. Ex. 15.)

He will testify that on December 14, 2009, Mrs. Sanchez was re-evaluated for urinary incontinence. He will testify that she reported losing urine with coughing, sneezing, movement, and intercourse and the need for a daily panty liner. She also again reported urinary frequency during the day, in addition to nocturia 2-3 times.

Mrs. Sanchez admitted in her deposition that her incontinence was severe, resulting in several episodes of "gushing" urine during activity, resulting in urine leakage onto her clothing. (Expert Rep., p. 10; Def. Ex. 15.) An exam was performed on this date, which confirmed a "large midline cystocele," indicating that the prolapse had possibly progressed since the previous visit. As reported in Dr. Wiltchik's deposition, this categorization indicates that Mrs. Sanchez was suffering from significant/severe prolapse. During this appointment, Mrs. Sanchez, who is a nurse, discussed with Dr. Wiltchik multiple different options to treat her conditions, including surgical and non-surgical options.

He will testify that Mrs. Sanchez admitted that conservative measures did not help. She also admitted that her pelvic floor complaints were affecting her quality of life. Specific to the prolapse, she reported experiencing dyspareunia, pelvic pressure, the feeling of a bulge in her vagina, difficulty having a bowel movement and general difficulty with intercourse. (Expert Rep., pp. 10-11; Def. Ex. 15.)

He will testify that during the pre-operative evaluation on January 6, 2010, Mrs. Sanchez' pelvic exam showed that the vagina had "no lesions, no excoriations, no abnormal discharge, large midline cystocele." The uterus was "anterior, no cervical motion tenderness, no fundal tenderness, normal size, shape and consistency." That visit states to the reader to "see dictated preoperative H&P". (Expert Rep., p. 17.) He will testify that when Mrs. Sanchez presented to Dr. Wiltchik on January 6, 2010 for a pre-operative evaluation. The exam again showed a "large midline cystocele." There was no mention of other forms of prolapse.

He will testify that Mrs. Sanchez expressed a desire for definitive surgical treatment, which was after one year and eight months of ongoing discussions with Dr. Wiltchick about her options. Mrs. Sanchez reaffirmed her desire for definitive treatment in a pre-operative visit on January 13, 2010. (Expert Rep., p. 10; Def. Ex. 15.) Mrs. Sanchez has admitted that conservative measures did not help. (Expert

Rep., pp. 10-11; Def. Ex. 15.) She also admitted that her pelvic floor complaints were affecting her quality of life. (Expert Rep., pp. 10-11; Def. Ex. 15.) Specific to the prolapse, she reported experiencing dyspareunia, pelvic pressure, the feeling of a bulge in her vagina, difficulty having a bowel movement and general difficulty with intercourse. (Expert Rep., pp. 10-11; Def. Ex. 15.)

He will testify that during the pre-operative evaluation on January 6, 2010, Mrs. Sanchez' pelvic exam showed that the vagina had "no lesions, no excoriations, no abnormal discharge, large midline cystocele." The uterus was "anterior, no cervical motion tenderness, no fundal tenderness, normal size, shape and consistency." That visit states to the reader to "see dictated preoperative H&P". (Expert Rep., p. 17.)

He will testify that Mrs. Sanchez presented to Dr. Wiltchik on January 6, 2010 for a pre-operative evaluation. The exam again showed a "large midline cystocele." There was no mention of other forms of prolapse. During this visit, the decision was made by Mrs. Sanchez and Dr. Wiltchik to proceed with a vaginal hysterectomy and bilateral sacrospinous ligament vaginal vault suspension using an anterior and posterior repair via the Pinnacle mesh kit. A pubovaginal sling with the Advantage Fit sling was also scheduled. Mrs. Sanchez subsequently signed an informed consent to have these procedures. Mrs. Sanchez knew that mesh would be used to address her pelvic floor complaints, and she understood the permanence of the mesh. By virtue of her medical background, she knew about mesh, specifically slings, and felt they were an important treatment option. (Expert Rep., p. 11.)

He will testify that on January 13, 2010, Mrs. Sanchez presented to Dr. Wiltchik for definitive therapy of her urinary incontinence and cystocele. Mrs. Sanchez was still losing urine with coughing, sneezing, and movement. She now said that her issue with urinating with intercourse, was "very" embarrassing and the "biggest issue" to her. Mrs. Sanchez also felt occasional fullness and pressure vaginally. Her husband reported that he "hits" something when they have intercourse.

On physical exam, Dr. Wiltchik found previous laparoscopic incisions and confirmed a "large midline cystocele." Dr. Wiltchik also noted on this visit that Mrs. Sanchez's uterus was "incompletely prolapsed." Dr. Davies will testify that Dr. Wiltchik has testified that she does not believe Mrs. Sanchez was an appropriate candidate for a pessary, and he agrees. (Expert Rep., p. 11; Wiltchik Dep. at 10:1-6.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing why surgical treatment was a necessary and appropriate treatment option for Mrs. Sanchez given her symptoms and conditions of SUI and POP.

- **Opinion # 7: Mrs. Sanchez was an appropriate candidate for the Pinnacle and Advantage Fit**

Dr. Davies will testify that he believes Mrs. Sanchez to a reasonable degree of medical certainty that Mrs. Sanchez was an appropriate candidate for the Pinnacle Pelvic Floor Repair System and the Advantage Fit. (Expert Rep., p. 11.) Mrs. Sanchez was an appropriate candidate for the Pinnacle Pelvic Floor Repair System and the Advantage Fit. (Expert Rep., p. 11.) Indeed, without surgical intervention, her conditions of prolapse and stress urinary incontinence likely would have worsened, while continuing to diminish her quality of life. The benefits outweighed the risks for her, and she was appropriately counseled on the potential risks of the Pinnacle and Advantage Fit devices. Mrs. Sanchez twice expressed a desire for "definitive treatment" and expressly opted for surgery, specifically complete pelvic floor reconstruction. (Expert Rep., pp. 17-18; Def. Ex. 15.)

Dr. Davies will testify regarding his opinion that Dr. Wiltchik testified that she was aware of the potential risks of the Pinnacle and Advantage Fit prior to Mrs.

Sanchez' pelvic mesh surgery and discussed the risks with Mrs. Sanchez. He will also testify that Dr. Wiltchik felt that she was properly trained to implant the Pinnacle and Advantage Fit, and she had a positive clinical experience with both. (Expert Rep., p. 8.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing why surgical treatment was a necessary and appropriate treatment option for Mrs. Sanchez given her symptoms and conditions of SUI and POP.

- **Opinion # 8: Mrs. Sanchez Understood the Risks and Provided Informed Consent For The Procedure**

He will testify that the benefits outweighed the risks for Mrs. Sanchez, and she was appropriately counseled on the potential risks of the Pinnacle and Advantage Fit devices. Mrs. Sanchez twice expressed a desire for "definitive treatment" and expressly opted for surgery, specifically complete pelvic floor reconstruction. (Expert Rep., pp. 11, 17-18; Def. Ex. 15.)

He will testify that Mrs. Sanchez admitted that conservative measures did not help. She also admitted that her pelvic floor complaints were affecting her quality of life. Specific to the prolapse, she reported experiencing dyspareunia, pelvic pressure, the feeling of a bulge in her vagina, difficulty having a bowel movement and general difficulty with intercourse. (Expert Rep., pp. 10-11; Def. Ex. 15.)

He will testify that Mrs. Sanchez expressed a desire for definitive surgical treatment, which was after one year and eight months of ongoing discussions with Dr. Wiltchick about her options. Mrs. Sanchez reaffirmed her desire for definitive treatment in a pre-operative visit on January 13, 2010. (Expert Rep., pp. 10, Exhibit

15.) Mrs. Sanchez has admitted that conservative measures did not help. (*Id.*) She also admitted that her pelvic floor complaints were affecting her quality of life. (*Id.*) Specific to the prolapse, she reported experiencing dyspareunia, pelvic pressure, the feeling of a bulge in her vagina, difficulty having a bowel movement and general difficulty with intercourse. (Expert Rep., pp. 10-11; Def. Ex. 15.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing why surgical treatment was a necessary and appropriate treatment option for Mrs. Sanchez given her symptoms and conditions of SUI and POP, and her understanding of the risks associated with each procedure before she agreed to proceed with the surgery. In addition, this opinion is relevant because it speaks to Boston Scientific's meeting of its duty of care in its warning of the risks associated with the Pinnacle.

- **Opinion # 9: Mrs. Sanchez's Pre-Implant Conditions Explain Her Current Pain Disorders**

He will testify that prior to the surgery giving rise to this case, Mrs. Sanchez suffered from two pelvic floor disorders, pelvic organ prolapse and stress urinary incontinence. Pelvic organ prolapse is a common problem for women. (Expert Rep., p. 1.)

He will testify regarding Mrs. Sanchez's long history of pelvic pain that predated her pelvic mesh surgery. He will also testify that she suffers from other pain disorders, including neuralgia affecting her left leg and foot, back pain, IBS, and ovarian/abdominal pain related to cysts. Mrs. Sanchez also experienced dyspareunia prior to her January 2010 surgery. He will testify that Mrs. Sanchez experiences no

new complaint today that did not predate her pelvic mesh surgery. He will testify that these pain disorders explain Mrs. Sanchez's complaints today. (Expert Rep., p. 19.)

He will testify that Mrs. Sanchez had a complicated medical history well before her pelvic mesh surgery. He will testify that she had delivered four children vaginally, which is a likely primary cause of her pelvic floor complaints. At the time of her January 2010 surgery, her medical history was positive for:

1. Factor 5 Leiden deficiency
2. History of Thrombosis
3. Hypertension
4. Hyperlipidemia
5. Irritable bowel syndrome with chronic constipation
6. Migraine headaches
7. Chronic lower back pain
8. History of ovarian cysts

(Expert Rep., p. 16; Def. Ex. 15.)

He will testify that as of January 2010 Mrs. Sanchez's past surgical history included:

Surgical History:

1. Tubal sterilization in 1998
2. Laparoscopic ovarian cystectomy in 2004
3. Multiple epidural injections for chronic back pain
4. Diagnostic hysteroscopy with D&C done in for menorrhagia in 2007
5. Therapeutic abortion

(Expert Rep., p. 16; Def. Ex. 15.)

He will testify that as of January 2010 Mrs. Sanchez's past medications included:

Medications:

1. Zocore 20 mg daily
2. Prithomax 50 mg twice daily

3. Asprin 81 mg Daily
4. Cymbalta 60 mg twice daily
5. Myospan 500mg daily
6. Laytension 10 mg daily
7. Wellbutrin SR 150mg twice daily

(Expert Rep., pp. 16-17; Def. Exs. 14, 15.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to establishing Mrs. Sanchez's preexisting medical conditions and how such medical conditions contribute to her current complaints. This testimony is relevant because it rebuts Plaintiffs' assertion that Plaintiffs' injuries are attributable to the Pinnacle.

- **Opinion # 10: The Pinnacle Is Not The Likely Cause of Mrs. Sanchez's Complaints of Erosion or Dyspareunia**

A. <u>The Operative Procedure</u>

He will testify that on January 13, 2010, Mrs. Sanchez was admitted for surgery and underwent the planned vaginal hysterectomy, bilateral sacrospinous ligament vaginal vault suspension, anterior and posterior repair with the Pinnacle, as well as placement of the Advantage Fit sling. The surgery also included a diagnostic cystoscopy. (Expert Rep., p. 11.) A levator myorrhaphy was performed, which involves plication of the levator ani muscles. In this type of repair, it is not the connective tissue on top of the rectum that is plicated from side-to-side side, but rather, the muscular tissue of the side wall is stitched on either side to meet in the midline. (Expert Rep., p. 12; Def. Ex. 15.)

He will testify that subsequent to January 13, 2010, Mrs. Sanchez had multiple follow up visits. According to the operative note, after Mrs. Sanchez underwent the vaginal hysterectomy, the peritoneum, but not the cuff, was closed. Dr. Wiltchik then moved on to the cystocele repair using some hydrodistension with 10 cc of lidocaine, and a vertical incision was made with the scalpel. A blunt dissection was used to tunnel out to the sacrospinous ligaments and the ischial spines. Sutures were placed on both sides to help anchor the mesh in its position. The mesh arms were placed into the sacrospinous ligaments. The operative note describes the lateral arms being placed but does not specifically mention them going in to the arcus tendineus. Proximal sutures were threaded through to keep the mesh in place proximally. Excess mesh was trimmed and it was tacked down with a single stitch in the midline distally near the urethra. (Expert Rep., p. 12; Def. Ex. 15.)

With both of these incisions now open (the vaginal cuff and the anterior repair incision), the rectocele was then addressed. It appears that the perineorraphy was dissected out and then a tunnel was made under the vaginal mucosa going up to the posterior aspect of the vaginal cuff. A piece of mesh previously trimmed for the original anterior apical was now placed over the rectocele all the way up to the vaginal cuff. The sides were anchored in place with a single stitch of 2-0 vicryl and all the defects began to be closed. The anterior vaginal mucosa was re-approximated with a single stitch of 0-vicryl and figure of eight sutures for hemostasis. Then the levator ani muscles were brought together in the midline, similar to a levator myorrhaphy. The posterior vaginal mucosa was trimmed and re-approximated with 0-vicryl in a running, locking stitch. After all of this, the standard procedure for placement of a synthetic suburethral sling was noted via a retropubic approach. (Expert Rep., p. 12; Def. Ex. 15.)

B. Mrs. Sanchez's Follow Up Care and Treatment

- 1/26/10 – The patient has a 2 week post-operative checkup and her pelvic exam showed the vagina is healing well, but bacterial vaginosis is diagnosed and oral clindamycin is used to treat it. Bacterial vaginosis is a clinical and/or microscopic diagnostic term referring to a shift in the vaginal bacteria from predominately lactobacilli to other bacteria, which are usually less commonly populating the vaginal flora. This is usually caused by the presence of foreign sutures in the vagina, which change the vaginal pH and can lead to bacterial vaginosis. Importantly, this diagnosis is not related to the use of the mesh in pelvic organ prolapse or incontinence surgery. It is just as common in surgeries using no mesh, such as native tissue repair procedures. In fact, most cases of bacterial vaginosis are unrelated to surgery and occur spontaneously in women, which again show that the use of the Pinnacle and Advantage Fit had no relation to this occurrence. (Expert Rep., p. 12; Def. Ex. 15.)
- 2/15/10 – The patient is 5 weeks post-operative complaining of a vaginal discharge that is tan- colored and foul smelling. She was treated this time with Flagyl. (Expert Rep., p. 12; Def. Ex. 15.)
- 2/23/10 – The patient has a 6 week post-operative checkup. She has a normal visit and all post-operative restrictions are lifted. She feels well and has completed her antibiotics and her discharge has resolved. She has no complaints. (Expert Rep., p. 12; Def. Ex. 15.)
- 4/9/10 – (office procedure) The patient is three months status post surgery and she has vaginal bleeding with a pink discharge necessitating the use of a panty liner daily. She is also feeling a scratchy sensation inside the vagina and requests definitive treatment. She has no pelvic pain, no dyspareunia, and no dysuria. On examination, there is a small amount of exposed mesh on the cuff at the nine o'clock position, which was excised and treated with silver nitrate.

There is also midline concern of the pending mesh erosion. She is started on estrogen vaginal replacement. (Expert Rep., p. 12; Def. Ex. 15.)

- 5/3/10 - (office procedure) The patient is now almost four months status post surgery. The discharge has resolved, there is no vaginal bleeding, no pelvic pain, and she feels well. On exam, there is again a small amount of exposed mesh at the nine o'clock, which is exactly the same position as it was at the last visit. It again was excised and silver nitrate was reapplied. Again the midline of the anterior mucosa is thin, which is concerning for a pending mesh erosion, but none is noted that day. She is to continue with the Vagifem intravaginally. (Expert Rep., pp. 12-13; Def. Ex. 15.)
- 5/20/10 – The patient is diagnosed with bacterial vaginosis and she is treated with metro gel intravaginally. (Expert Rep., p. 13; Def. Ex. 15.)
- 6/14/10 - The patient is now five months status post surgery. She reports a decent amount of vaginal discharge that is pink tinged. She has been using the Vagifem without improvement. On exam, there is a large amount of exposed mesh in the midline and large amounts of pink tinged discharge. There is no discomfort. (Expert Rep., p. 13; Def. Ex. 15.)
- 6/18/10 – (hospital procedure) The patient undergoes excision of exposed mesh in the operating room and a 5mm portion of mesh was excised while the vagina epithelium was undermined and then approximated. (Expert Rep., p. 13; Def. Ex. 15.)
- 7/2/10 - The patient was two weeks status post operative excision of mesh exposure. As expected, she had some vaginal discharge that was bloody but she had no pain with urination. (Expert Rep., p. 13; Def. Ex. 15.)
- 7/16/10 – The patient is about four weeks out from her vaginal mesh erosion excision. At this visit, the patient reported feeling well. There is no abnormal vaginal bleeding or vaginal discharge and no pain with urination. On exam, the

excisions were all well healed and the mesh was not exposed. (Expert Rep., p. 13; Def. Ex. 15.)

- 9/1/10 - (office procedure) The patient re-presented approximately two and a half months out from her vaginal mesh exposure excision. She complained of abnormal vaginal bleeding and a small amount of pink discharge. She also has discomfort with intercourse and she stated that her husband cannot fully penetrate her due to her pain. She has no dysuria and no other pelvic pain. On exam there is a midline defect noted of exposed mesh. The mesh is excised in the office and silver nitrate is applied. (Expert Rep., p. 13; Def. Ex. 15.)
- 9/17/10 – The patient presents approximately two and a half weeks later with no complaints, but does have some spotting and discharge. On her gynecological exam, a large area of mesh is exposed in the midline and is bleeding. She is now scheduled for a repeat attempt at excision and closure in the operating room. (Expert Rep., p. 13; Def. Ex. 15.)
- 10/4/10 – The patient is seen for preoperative visit to arrange for excision procedure. Again, the exposure area in the midline is appreciated and the mucosa is bleeding. The patient is scheduled for the mesh excision. A perineorrhaphy is also scheduled for the same time, despite the fact there are no complaints of outlet relaxation syndrome and no noted abnormalities on the pelvic exam. (Expert Rep., pp. 13-14; Def. Ex. 15.)
- 10/12/10 - (hospital procedure) The patient undergoes excision of exposed mesh and a perineorraphy. There is an indication for the vaginal mesh excision, but there is no indication given for the perineorraphy. During the course of the surgery not only is the mesh excised as well as the perineorraphy performed, but excess vaginal mucosa was trimmed away and the defect was closed. (Expert Rep., p. 14; Def. Ex. 15.)

- 10/26/10 - The patient returned for a two week post-operative visit complaining of a foul vaginal discharge, but no vaginal bleeding, pelvic pain, or dysuria. She is treated for bacterial vaginosis with Flagyl. (Expert Rep., p. 14; Def. Ex. 15.)
- 11/15/10 - The patient is now approximately five weeks status post second vaginal mesh excision in the operating room. She complains of abnormal vaginal bleeding daily for the past week and has an odor. On examination, she is found to have a blood tinged thick discharge. She is started on metro gel intravaginally to treat this. (Expert Rep., p. 14; Def. Ex. 15.)
- 11/23/10 - The patient is now approximately six weeks out from her second vaginal mesh erosion excision in the operating room. There is no further bleeding or discharge and she has no complaints. On examination, all incisions appear to be well healed. She is now allowed to resume all activities without restrictions. (Expert Rep., p. 14; Def. Ex. 15.)
- 4/11/11 - (office procedure) The patient is now approximately a year and quarter out from her original surgery and six months out from her second vaginal mesh erosion excision in the operating room. She complains of abnormal vaginal bleeding which she reports becomes worse after intercourse. She also has pelvic pain and sensations that her bladder is weak. On exam, there is a 1-2 cm midline defect with exposed mesh, which is excised and again silver nitrate is applied. She was started on Vagifem and instructed to refrain from intercourse. A LEEP procedure was planned in the office. (Expert Rep., p. 14; Def. Ex. 15.)
- 4/25/11 - The patient underwent a LEEP procedure in the office to excise the areas of mesh exposure. The patient is to return for follow up in the near future. (Expert Rep., p. 14; Def. Ex. 15.)

- 5/11/11 - The patient returns for a post LEEP follow up. The discharge was almost gone at this time. The patient was feeling well. On exam, exposed mesh was not seen and no discharge was appreciated. She is to continue to follow up as needed. (Expert Rep., p. 14; Def. Ex. 15.)
- 5/23/11 - The patient returns and reports no discharge and no pain. She is using the Vagifem regularly and has no complaints. On exam, no areas of exposed mesh are noted. She will continue with the Vagifem twice weekly and a return visit was scheduled. (Expert Rep., p. 14; Def. Ex. 15.)
- 7/8/11 - (office procedure) The patient again has a vaginal discharge that is blood tinged. There is no pain, but she reports that her husband does note during intercourse a sensation she attributes to exposed mesh on occasion. On examination, small areas of mesh protruding through the vaginal mucosa anteriorly were appreciated, but in random areas not just in the midline. The previous areas of exposed mesh are now well covered. The exposed mesh areas are trimmed with scissors and silver nitrate applied. Patient was to follow up in two weeks. (Expert Rep., p. 15; Def. Ex. 15.)
- 8/30/11 - The patient again has vaginal abnormal bleeding. She is using her Vagifem regularly and she reports that her husband states that sensation she attributes to the exposed mesh has improved. The patient is concerned that her bladder is falling down. On exam, there is a small area of mesh protruding through the anterior mucosa in the midline. The previous areas of exposed mesh are now well covered. At this point the patient is to continue her present treatment. (Expert Rep., p. 15; Def. Ex. 15.)
- 10/17/11 - (office procedure) The patient presents two months later. She still has a brownish discharge and some discomfort with intercourse. She is still using the Vagifem regularly. She is experiencing more pressure when she performs valsalva and worries that her prolapse has returned. On examination

there is a 1 cm midline defect of exposed mesh, which again was excised and silver nitrate was applied. At this point, she will continue her Vagifem tablets twice weekly and will return to have more mesh excised in the office. (Expert Rep., p. 15; Def. Ex. 15.)

- 8/29/12 - (office procedure) The patient again presents with problems with vaginal discharge with a pink tinge to it and discomfort with intercourse due to exposed mesh. She reports her husband can occasionally feel what she interprets as the exposed mesh. She also notes that her bladder is dropping. On examination there is a small 1cm area of exposed mesh in the mid line adjacent to the vaginal cuff. It is excised and silver nitrate is applied. A small cystocele is noted. Patient will continue treatment plan and will return to the office as needed. (Expert Rep., p. 15; Def. Ex. 15.)
- 2/6/13 - (office procedure) The patient again has vaginal discharge with occasional spotting and rarely notices an odor. She reports that her husband barley feels any abnormalities with intercourse. She denies any pelvic pain or incontinence. On the gynecological exam, multiple areas of exposed mesh anteriorly in a random pattern are appreciated not only in the midline. These exposed areas are excised with scissors and silver nitrate is applied. She is again encouraged to return regularly so the areas can be treated. (Expert Rep., p. 15; Def. Ex. 15.)
- 5/21/13 - (office procedure) The patient presents again, now three months out from her last visit. She again has discharge that is pink tinged. She feels some more cramping and has not been using the vaginal estrogen. She has not let her problems interfere with normal activity. She has no dyspareunia or pain with urination. On exam, there are multiple areas of exposed mesh anteriorly near the vaginal cuff in a random pattern on both sides of the midline. These areas were again excised with scissors and silver nitrate applied. She is encouraged

to use the Vagifem to promote healing over the exposed mesh areas. (Expert Rep., pp. 15-16; Def. Ex. 15.)

- 11/21/13 - Dr. Margolis, expert witness for the Mr. and Mrs. Sanchez, examined Mrs. Sanchez which revealed a cystourethrocele (not graded) and a positive stress test. In addition, he notes "there is a large wide area of mesh erosion through the anterior vaginal wall." (Expert Rep., p. 16; Def. Ex. 15.)

C. Mesh Erosion Is Not Evidence Of A Defect In The Pinnacle or Advantage.

Dr. Davies will explain that when one talks about mesh erosion (which is actually mesh exposure), mostly physicians are referring to a small opening at the vaginal incision where the mesh is now exposed to the lumen of the vagina. Dr. Davies will testify that he views mesh exposure as a healing issue, and that mesh exposure is not an indication of a defect in the device. He will testify that in many cases the exposure is asymptomatic and can be treated with estrogen cream or excision in the office. (Expert Rep., p. 9.)

D. Mrs. Sanchez Was At Higher Risk For Mesh Erosion Because The Pinnacle Was Placed In The Wrong Plane

Dr. Davies will testify that there is an increased risk of erosion and poor healing is if the mesh is located in the wrong surgical plane. Even in the best of surgical hands, mesh malplacement can occur. If mesh is located in a superficial plane, the patient is at higher risk for erosion. (Expert Rep., p. 18; Def. Ex. 15; Davies Dep. at 209:5-12, 209:23-212:1, 212:13-213:5, 214:1-18, 218:24-220:2; 221:7-223:18, 224:3-22, 379:8-15; Karamitsos Dep. at 87:20-23, 87:25-88:1, 88:5-90:9, 97:20-98:2, 105:4-7, 105:9-10, 105:11-15, 105:17-21, 105:23-106:11, 106:13-18, 107:13-18, 107:20-21,108:10-13, 108:15.) He will testify that Mrs. Sanchez' surgical mesh was located in the wrong surgical plane. (Expert Rep., p. 18; Def. Ex. 15, Davies Dep. at 209:5-12, 209:23-212:1, 212:13-213:5, 214:1-18, 218:24-220:2; 221:7-223:18, 224:3-22,

379:8-15; Karamitsos Dep. at 87:20-23, 87:25-88:1, 88:5-90:9, 97:20-98:2, 105:4-7, 105:9-10, 105:11-15, 105:17-21, 105:23-106:11, 106:13-18, 107:13-18, 107:20-21,108:10-13, 108:15.)

Dr. Davies relies on the following statements of Dr. Karamitsos in coming to his opinion:

Dr. Karamitsos's testimony that Dr. Wilchik did not perform a hydrodissection during the implant procedure. Karamitsos Deposition at 54:21–24. Dr. Wilchik instead used a sharpened blunt dissection. *Id.* at 55:23–54:3. It is Dr. Karamitsos' custom and practice to perform a hydrodissection. *Id.* at 55:5-9. A hydrodissection generally injects saline into the plane of tissue that the implanter intends to place the mesh. *Id.* at 55:21–22.

Dr. Karamitsos's testimony that she employs more hydrodissection than Dr. Wiltchik performed on Mrs. Sanchez during the implant procedure. Karamitsos Dep. at 87:20–88:10. Dr. Karamitsos will testify that she would typically infiltrate up to 60 cc's of injectable saline into the anterior and posterior spaces, which is more fluid than Dr. Wiltchik used in Mrs. Sanchez's procedure. *Id.* at 88:12–89:6. The medical records will show that Dr. Wiltchik only used 10 cc's of lidocaine, which Dr. Karamitsos will testify is not sufficient. *Id.* at 105:4–106:18, 107:13–21. As she will describe, Dr. Karamitsos' method opens up the space, allowing her to see if it blanches; thereby visualizing whether the opening was too superficial. Using hydrodissection, if she could see more of a rise overall, it would be indicative of a space that is deeper and more appropriate for mesh placement. *Id.* at 88:14–20. Dr. Karamitsos will testify that using less volume for hydrodissection could lead to superficial placement of the device (*Id.* at 108:10–15), and that if she witnessed Dr. Wiltchik not performing a hydrodissection for Mrs. Sanchez's procedure today, she would tell her that she thinks Dr. Wiltchik should use hydrodissection to dissect. *Id.* at 97:20–23.

Dr. Davies will testify that Mrs. Sanchez had a LEEP procedure done on April 25, 2011. Use of the thermal wire loop in a LEEP procedure could very easily cause damage to the bladder wall with the potential for an immediate or delayed creation of a vesicovaginal fistula. The fact that this procedure was done and no bladder injury occurred supports my opinion that the mesh was located in a plane that was too superficial, thereby further away from the bladder which escaped injury from the thermal electrode of the LEEP procedure. (Expert Rep., p. 18; Davies Dep. at 370:9-374:6; Def. Ex. 15.) Dr. Davies will testify that he has not seen or heard about physicians utilizing a LEEP procedure to address a mesh excision. Davies Dep. at 374:7-18.)

E. Mrs. Sanchez Was At Higher Risk For Mesh Erosion Because Erosion Is More Likely With Performance of Hysterectomy With A Mesh-Based Repair Increases Risk of Erosion

He will testify that the performance of a hysterectomy at the same time as a mesh-based repair is a risk factor for erosion. (Expert Rep., p. 18; Davies Dep. at 195:5-196:16; Risk factors for mesh extrusion after prolapse surgery: a case-control study. Female Pelvic Medicine & Reconstructive Surgery, Ghafar, E, et al. 18(6):357-61 (Nov.-Dec. 2012).) Even in his own research at The Penn State Milton S. Hershey Medical Center, which was presented at the American Urogynecological Society meeting in October 2012, the data on anterior/apical prolapse repair with mesh showed a higher incidence of mesh exposure if concomitant hysterectomy was performed compared to no hysterectomy. (Pre-operative risk factors for mesh erosion in patients undergoing anterior/apical vaginal prolapse repair—a retrospective analysis, Diemling, T, et al., Poster presentation at American Urogynecologic Society Annual Meeting (Oct. 2012).) Given that Mrs. Sanchez underwent a concomitant hysterectomy and mesh-based prolapse repair, she was at increased risk for mesh exposure or erosion. (Expert Rep., p. 18; Def. Ex. 15.)

F. Mrs. Sanchez Was At Higher Risk For Mesh Erosion Because It Is More Likely With A Midline Vertical T-Incision

He will testify that there is an increase in the risk of mesh erosion because of the use of the midline vertical incision used in the anterior colporrhaphy, especially if this incision joins the incision for the hysterectomy in a way that we refer to as a T-incision. The Junction of the 'T' has the poorest vascular supply and thus puts a patient at risk for mesh erosion. (Expert Rep., p. 18; Def. Ex. 15.)

G. Mrs. Sanchez Was At Higher Risk For Mesh Erosion Because It Is More Likely To Occur In Anterior Repairs Than In Posterior Repairs

He will testify that mesh erosion is more likely in anterior repairs than in posterior repairs. He will testify that if a property of the mesh was the problem, there should not be a difference. Instead, it is well known that the nature of the vaginal lining under the bladder is a thinner tissue than the vaginal tissue over the rectum. Hence, placing the mesh under a thicker layer of tissue (posteriorly over a rectocele) leads to less mesh erosion than placing it under thinner tissue (anteriorly under a cystocele). These concepts also explain why native tissue repairs of rectoceles have a lower failure rate than native tissue repairs of cystoceles. (Expert Rep., pp. 19-20; Def. Ex. 15.)

H. Mrs. Sanchez's Dyspareunia Is Most Likely Caused By Performance Of Perineorrhaphy and/or Levator Myorrhaphy

He will testify that in regards to the complaint of dyspareunia (a condition noted in 2008 before her pelvic floor surgery), the performance of the perineorrhaphy places Mrs. Sanchez at a higher risk of that complication. While areas of mesh erosion can lead to dyspareunia, Mrs. Sanchez has also had two procedures done relatively close together in time that can themselves lead to dyspareunia. She has had either a perineorrhaphy and/or levator myorrhaphy done on two occasions during this time frame. The first was done at the original repair and the second was done at her second

mesh excision procedure in October 2010. While some of the operative reports describe the procedure as a perineorrhaphy, the use of the levator muscles being brought across the midline suggests that it was a levator myorrhaphy. In his years of experience and by review of the literature, doing one of these procedures will place a patient at increased risk of dyspareunia. This is particularly true for the second procedure in which she was already complaining of dyspareunia. (Expert Rep., p. 20; Def. Ex. 15.)

He will testify that the more likely cause for her partner's inability to fully penetrate during intercourse is the performance of not one, but two, perineorrhaphies or levator myorrhaphies. These procedures narrow the vaginal caliber or lumen, thus making it seem like the vagina is short, and a partner cannot fully penetrate without pain to the woman. (Expert Rep., p. 20; Def. Ex. 15.) He will explain that scarring and shortening associated with the mesh has never been described in Mrs. Sanchez's records nor in the exam provided by the plaintiff's expert, Dr. Margolis. (Expert Rep., p. 20; Def. Ex. 15.)

Additionally, in the procedure describing the intraoperative excision and closure of the mesh erosion, the records describe the cutting away the excess vaginal mucosa. Given that some vaginal mucosa was missing from the vaginal wall at that location, it is unlikely that there would be any excess vaginal mucosa at all. Trimming away of vaginal mucosa likely inhibited Mrs. Sanchez' healing process. (Expert Rep., p. 20; Def. Ex. 15.)

Beyond the specific exhibits, expert report, and testimony references above, Dr. Davies will also base this opinion on his more than 20 years of clinical experience as a urogynecologist, his medical education, and his review and knowledge of the medical literature. This testimony is relevant to explaining Mrs. Sanchez's surgical procedure, and the medical care and treatment in connection with the Pinnacle and Advantage devices. This testimony is also relevant because it rebuts Plaintiffs' assertion that

Plaintiffs' injuries are attributable to a defect in the Pinnacle. This testimony also explains that Mrs. Sanchez's complications are more likely attributable to alternative causes, and rebuts Plaintiffs' assertion that Plaintiffs' injuries are attributable to the Pinnacle.

## IV. Additional Documents Boston Scientific May Use During Dr. Davies's Testimony To Support His Opinions:

While Boston Scientific does not anticipate the need to use the majority of these documents, the following list reflects all documents relied upon by Dr. Davies in forming his opinions. In addition, as a urogynecologist and surgeon, Dr. Davies is familiar with additional articles in the medical literature, as reflected below.

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| Pinnacle Pelvic Floor Repair Kits Anterior/Apical Directions for Use | Boston Scientific Corp. | 12/12/07 | | 6 | 5 |
| Directions For Use – Advantage Fit | BSC | | | 7 | 5 |
| AUGS Position Statement | | 2014-01-07 | | 54 | 1 - 10 |

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| Pelvic Floor Repair Kit Clinical Experience Summary Ver. AG dated 11-13-2012. | | | BSC M082 0000 5433-21 | 197 | 1 - 10 |
| Pelvic Floor Repair Kit Clinical Experience Summary Ver. AH dated 2-13-2013. | | | BSC M082 0000 8749-839 | 198 | 1 - 10 |
| Boston Scientific internal memo dated 11-10-2006 titled Sling Choices for Treatment of Female Stress Urinary Incontinence. | | | BSC M053 0005 0858-9 | 199 | 1 - 10 |
| Advantage Family Risk Analysis Report Ver. AJ dated 7-19-2001. | | | BSC M031 0000 6382-468 | 200 | 1 - 10 |

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| Pinnacle Pelvic Floor Repair Kit Clinical Risk/Benefit Analysis Ver. AB dated 6-10-2008. | | | BSC M038 0000 8712-238 | 201 | 1 - 10 |
| Pinnacle Pelvic Floor Repair Kit Clinical Risk/Benefit Analysis Ver. AC dated 11-20-2008. | | | BSC M038 0000 8766-794 | 202 | 1 - 10 |
| Pinnacle Pelvic Floor Repair Kit Clinical Risk/Benefit Analysis Ver. AD dated 3-6-2009. | | | BSC M038 0000 8795-820 | 203 | 1 - 10 |
| Pinnacle Pelvic Floor Repair Kit Clinical Risk/Benefit Analysis Ver. AE dated 6-24-2009. | | | BSC M019 0000 5348-375 | 204 | 1 - 10 |
| Memos to File from Walsh re Capio/Pinnacle | | 2009-09-09 | | 259 | 1 - 10 |
| Polyform CRBA Version 2 | | 2012-03-12 | | 330 | 1 - 10 |
| Memo from Walsh re: Patient Risk | | 2009-10-16 | | 354 | 1 - 10 |

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| Email re: SGS Pinnacle Study | | 2010-03-11 | | 357 | 1 - 10 |
| Email re: Fellows Study | | 2010-03-17 | | 358 | 1 - 10 |
| Multi-Center Retrospective Clinical Evaluation of the Long Term Outcomes Following Pelvic Organ Prolapse Repair Using Pinnacle PFR Kit, IUGA | Dr. Peter Rosenblatt | 2012-04-06 | BSC M052 0002 0153-55 | 359 | 1 - 10 |
| AUGS Position Statement on Restrictions of Surgical Options forPFD FINAL.pdf | AUGS | 2013-03-26 | BSC M062 0027 6064-68 | 390 | 1 - 10 |
| Exemplar - Protegen | BSC | | | 410 | 1 - 10 |
| Pinnacle PFR Kit Clinical Risk/Benefit Analysis Ver. AA. | | | BSC M038 0000 8693-711 | 211 | 1 - 10 |
| Multi-Center Retrospective Clinical Evaluation of | P. Rosenblatt | | BSC M052 0002 | 359 | 1 - 10 |

| Title | Author | Date | Bates Range | Def. Ex. | Opinions Supported |
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| the Long Term Outcomes Following Pelvic Organ Prolapse Repair Using Pinnacle PFR Kit (Abstract), IUGA. | | | 0153-55 | | |
| AUGS Statement | AUGS | 2013-03-26 | BSCM062 0027 6069-71 | 391 | 1 - 10 |
| AUGS Position Statement | AUGS | 2014-01-03 | | 392 | 1 - 10 |
| IUGA Position Statement | IUGA | | | 393 | 1 - 10 |
| Position Statement on Mesh Mid-Urethral Slings for Stress Urinary Incontinence | | AUA | | 394 | 1 - 10 |
| R de Tayrac, A. Gervaise and H. Fernandez, *Cure De Cycstocele Voie Basse Par Prothese Sous-Vesicale Libre,* J Gynecol Obstet Biol Reprod | | | | 412 | 1 - 10 |

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Dated: April 20, 2015

Respectfully submitted,

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**PROOF OF SERVICE**

I am employed in the County of Orange, State of California. I am over the age of 18 and not a party to the within action. My business address is 5 Park Plaza, Suite 1600, Irvine, California 92614.

On April 20, 2015, I served on the interested parties in said action the within:

**DEFENDANT'S OFFER OF PROOF FOR EXPERT WITNESS**

**MATTHEW DAVIES, M.D.**

by placing a true copy thereof in a sealed envelope(s) addressed as stated on the attached mailing list.

☒ (MAIL) I am readily familiar with this firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. postal service on that same day in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than 1 day after date of deposit for mailing in affidavit.

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on April 20, 2015, at Irvine, California.

| Eva M. Weiler | /s/ Eva M. Weiler |
|---|---|
| (Type or print name) | (Signature) |

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